

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. 22-513 (RGA)
)	
TEVA PHARMACEUTICALS INC. and)	
TEVA PHARMACEUTICALS USA, INC.,)	
)	
Defendants.)	

**PLAINTIFF’S ANSWER TO DEFENDANTS TEVA PHARMACEUTICALS INC. AND
TEVA PHARMACEUTICALS USA, INC.’S COUNTERCLAIMS**

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), in response to the counterclaims of Defendant Teva Pharmaceuticals Inc. and Teva Pharmaceuticals USA, Inc. (collectively “Teva”) filed on July 12, 2022 (D.I. 12) (“Teva’s counterclaims”), hereby states as follows, in like-numbered paragraphs:

To the extent not specifically admitted herein, the allegations of Teva’s counterclaims are denied.

Unless otherwise specified, the terms used herein reflect the definitions provided in Otsuka’s Complaint (D.I. 1).

THE PARTIES

1. Upon information and belief, Otsuka admits the allegations in paragraph 1 of Teva’s counterclaims.

2. Otsuka admits the allegations of paragraph 2 of Teva’s counterclaims.

JURISDICTION AND VENUE

3. Otsuka admits that Teva purports to state counterclaims pursuant to 28 U.S.C. §§ 2201 and 2202, but denies that Teva is entitled to any of the relief it seeks.

4. Otsuka admits the allegations of paragraph 4 of Teva's counterclaims.

5. Otsuka admits that venue is proper in this judicial district under 28 U.S.C. § 1391, but denies the remaining allegations in paragraph 5 of Teva's counterclaims.

6. The allegations of paragraph 6 contain legal conclusions to which no response is required. To the extent a response is required, Otsuka admits that an actual controversy exists between Teva and Otsuka regarding Teva's infringement of claims of the patents in suit. Otsuka denies that Teva is entitled to any of the relief it seeks and denies all remaining allegations of paragraph 6.

7. Otsuka admits the allegations of paragraph 7 of Teva's counterclaims.

8. Otsuka admits the allegations of paragraph 8 of Teva's counterclaims.

9. Otsuka admits the allegations of paragraph 9 of Teva's counterclaims.

10. Otsuka admits the allegations of paragraph 10 of Teva's counterclaims.

11. Otsuka admits the allegations of paragraph 11 of Teva's counterclaims.

12. Otsuka admits the allegations of paragraph 12 of Teva's counterclaims.

13. Otsuka admits the allegations of paragraph 13 of Teva's counterclaims.

14. Upon information and belief, Otsuka admits the allegations of paragraph 14 of Teva's counterclaims.

15. Upon information and belief, Otsuka admits that Teva's ANDA No. 216933 contains a statement alleging that Teva will not infringe any valid and enforceable claim of the

'730 patent or the '694 patent by the manufacture, use, importation, offer for sale, or sale of its generic tolervaptan products. Otsuka denies these assertions.

16. Otsuka admits that it received a letter sent by Teva, dated March 8, 2022, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 216933 pursuant to § 505 (j)(2)(B) of the FDCA and 21 C.F.R. § 314.95 ("Notice Letter"). Otsuka denies the remaining allegations of paragraph 16 of Teva's counterclaims.

17. Otsuka admits the allegations of paragraph 17 of Teva's counterclaims.

18. Otsuka admits the allegations of paragraph 18 of Teva's counterclaims.

COUNT I – DECLARATORY JUDGMENT OF NONINFRINGEMENT
(US PATENT NO. 8,501,730)

19. Otsuka incorporates its responses to each of the preceding paragraphs as if set forth herein.

20. Otsuka admits that an actual controversy exists between Otsuka and Teva regarding Teva's infringement of the '730 patent, but denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 20.

21. Otsuka denies the allegations in paragraph 21 of Teva's counterclaims.

22. Otsuka denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations in paragraph 22 of Teva's counterclaims.

COUNT II – DECLARATORY JUDGMENT OF NONINFRINGEMENT
(US PATENT NO. 10,905,694)

23. Otsuka incorporates its responses to each of the preceding paragraphs as if set forth herein.

24. Otsuka admits that an actual controversy exists between Otsuka and Teva regarding Teva's infringement of the '694 patent, but denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 24.

25. Otsuka denies the allegations in paragraph 25 of Teva's counterclaims.

26. Otsuka denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations in paragraph 26 of Teva's counterclaims.

COUNT III – DECLARATORY JUDGMENT OF NONINFRINGEMENT
(US PATENT NO. 8,273,735)

27. Otsuka incorporates its responses to each of the preceding paragraphs as if set forth herein.

28. Otsuka admits that an actual controversy exists between Otsuka and Teva regarding Teva's infringement of the '735 patent, but denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 28.

29. Otsuka denies the allegations in paragraph 29 of Teva's counterclaims.

30. Otsuka denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations in paragraph 30 of Teva's counterclaims.

COUNT IV – DECLARATORY JUDGMENT OF INVALIDITY
(US PATENT NO. 8,501,730)

31. Otsuka incorporates its responses to each of the preceding paragraphs as if set forth herein.

32. Otsuka admits that an actual controversy exists between Otsuka and Teva regarding the validity of the '730 patent, but denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 32.

33. Otsuka admits that Teva's Notice Letter includes a section purporting to be a "Detailed Statement Of The Factual And Legal Bases That U.S. Patent Nos. 8,501,730 and 10,905,694 are Invalid, Unenforceable or Not Infringed," wherein Teva alleges that one or more claims of the '730 Patent are invalid. Otsuka denies these assertions.

34. Otsuka denies the allegations in paragraph 34 of Teva's counterclaims.

35. Otsuka denies the allegations in paragraph 35 of Teva's counterclaims.

36. Otsuka denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations in paragraph 36 of Teva's counterclaims.

COUNT V – DECLARATION OF INVALIDITY
(US PATENT NO. 10,905,694)

37. Otsuka incorporates its responses to each of the preceding paragraphs as if set forth herein.

38. Otsuka admits that an actual controversy exists between Otsuka and Teva regarding the validity of the '694 patent, but denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 38.

39. Otsuka admits that Teva's Notice Letter includes a section purporting to be a "Detailed Statement Of The Factual And Legal Bases That U.S. Patent Nos. 8,501,730 and 10,905,694 are Invalid, Unenforceable or Not Infringed," wherein Teva alleges that one or more claims of the '694 Patent are invalid. Otsuka denies these assertions.

40. Otsuka denies the allegations in paragraph 40 of Teva's counterclaims.

41. Otsuka denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations in paragraph 41 of Teva's counterclaims.

COUNT VI – DECLARATION OF INVALIDITY
(US PATENT NO. 8,273,735)

42. Otsuka incorporates its responses to each of the preceding paragraphs as if set forth herein.

43. Otsuka admits that an actual controversy exists between Otsuka and Teva regarding the validity of the '735 patent, but denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 43.

44. Otsuka denies the allegations in paragraph 44 of Teva's counterclaims.

45. Otsuka denies the allegations in paragraph 45 of Teva's counterclaims.

46. Otsuka denies that Teva is entitled to any of the relief it seeks and denies the remaining allegations in paragraph 46 of Teva's counterclaims.

REQUEST FOR RELIEF

WHEREFORE, Otsuka denies that Teva is entitled to the judgment and relief requested in Teva's counterclaims, and respectfully requests that this Court enter judgment in Otsuka's favor and against Teva on the counterclaims set forth above and respectfully requests that this Court:

- A. dismiss Teva's counterclaims with prejudice;
- B. deny any of the relief Teva seeks in its counterclaims;
- C. grant Otsuka the relief it requests in its Complaint; and
- D. award Otsuka such further and additional relief as this Court deems just and proper.

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CERTIFICATE OF SERVICE

I hereby certify that on August 2, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 2, 2022, upon the following in the manner indicated:

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